

**REMARKS**

The Office Action dated July 9, 2003 presents the examination of claims 1-23. Claims 5 and 13 are withdrawn from consideration. Claims 1-4, 6-12, and 14-23 are rejected. Claims 5, 8-10, 13, and 21-23 are canceled herein. Claims 1-4, 6-7, 11-12, 14-16, 18, and 20 are amended. Claim 24 is added. Support for claim 24 is found in the specification, such as on page 4, line 3 to page 6, line 10. No new matter is inserted into the application.

***Request for Initialed Form PTO-1449***

Applicants filed an Information Disclosure Statement (IDS) on March 4, 2002. The Examiner has yet to acknowledge the references listed on the form PTO-1449 attached to the IDS. The Examiner is respectfully requested to consider the references therein, and sign, initial, and return to Applicants the form PTO-1449 as evidence of his consideration of the references. A copy of the form PTO-1449 is attached hereto for the Examiner's convenience.

***Election/Restriction***

The Examiner maintains the restriction requirement such that claims 5 and 13 are withdrawn from consideration. Claims 5 and 13 are canceled, thus rendering the restriction requirement moot.



***Claim Objections***

The Examiner objects to claim 18 for being in improper multiple-dependent form. Claim 18 is amended to depend from claim 1. Thus, the instant objection is overcome.

***Rejection under 35 U.S.C. § 112, first paragraph***

The Examiner rejects claims 17-19 under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter not enabled by the specification. Claims 17 and 19 are canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection applied to pending claim 18. Reconsideration of the claim and withdrawal of the instant rejection are respectfully requested.

Specifically, the Examiner asserts that although the specification enables the treatment of rheumatoid arthritis, the specification fails to enable the prevention of any disease. In response to the Examiner's remarks, the term "preventing" is deleted from claim 18. Thus, the instant rejection is overcome.

Nevertheless, Applicants wish to address the Examiner's assertion that there is nothing in the specification regarding how the *in vitro* data correlates to the treatment of disorders. Applicants enclose herewith literature and abstracts which disclose the relationship between ulcerative colitis or systemic lupus



erythematosus and Th2 response. Please see Exhibits 1-3 attached hereto. From these papers, the skilled artisan can easily understand that the compounds of the present invention can be utilized for the treatment of ulcerative colitis or systemic lupus erythematosus. The instant specification also provides enablement for a treating agent of lupus nephritis since lupus nephritis is a symptom of systemic lupus erythematosus.

***Rejection under 35 U.S.C. § 112, second paragraph***

The Examiner rejects claims 4, 6, 7, 19, 20, 21, 22, and 23 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Claims 19 and 21-23 are canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection applied to pending claims 4, 6-7, and 20. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

1. The Examiner notes that the limitation of "wherein both  $V^1$  and  $V^2$  are single bonds" recited in claim 4 does not have antecedent basis in claim 1. Applicants amend claim 1 to recite "both  $V^1$  and  $V^2$  are single bonds or one of  $V^1$  and  $V^2$  is



a single bond and the other is -O-,...." Thus, the rejection is overcome.

2. The Examiner notes that the limitation of "ring C is an optionally substituted 5- or 6-membered heterocyclic ring" recited in claim 6 does not have antecedent basis in claim 5. First, claim 6 is amended into independent form. Second, however, the claim is amended to state that ring C is an optionally substituted pyridine ring. Support for this amendment is found in the specification, such as on page 5, lines 18-19.
3. The Examiner states that claim 5 does not provide antecedent basis for the recitation of "each of rings A, B and C are independently benzene..." recited in claim 7. Claim 7 is amended into independent form. Thus, the rejection is overcome.
4. The Examiner points out that claim 1 does not provide proper antecedent basis for claims 19 and 20. Claim 19 is canceled, and claim 20 is amended into independent form. Thus, the rejection is overcome.
5. Claims 21 and 22 are canceled.



6. The Examiner states that claim 5 does not provide antecedent basis for the recitation of "ring C is an optionally substituted 6-membered heterocyclic ring" recited in claim 23. Claim 23 is canceled. Thus, the rejection is overcome.

Applicants respectfully submit that the instant claims fully comply with 35 U.S.C. § 112, second paragraph. Withdrawal of the instant rejection is therefore respectfully requested.

***Rejection under 35 U.S.C. § 101***

The Examiner rejects claims 21 and 22 under 35 U.S.C. § 101 for being directed to non-statutory subject matter. Claims 21 and 22 are canceled, thus rendering the rejection thereof moot.

***Rejection under 35 U.S.C. § 102***

The Examiner rejects claims 1-4, 6-12, and 14-23 under 35 U.S.C. § 102(a) for allegedly being anticipated by Tanimoto '829 (WO 99/38829). Claims 8-10, 17, 19, and 21-23 are canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection applied to pending claims 1-4, 6-7, 11-12, 14-16, 18, and 20. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.



In order to overcome this rejection, Applicants submit herewith a verified translation of the priority document, JP 209298/1999. The priority document was filed in Japan on July 23, 1999. Tanimoto's effective date is August 5, 1999. Thus, Tanimoto '829 is not prior art against the present application. Withdrawal of the instant rejection is therefore respectfully requested.

***Double Patenting***

The Examiner rejects claims 1-4, 6-12, and 14-23 under the doctrine of double patenting over Tanimoto '817 (U.S. Patent 6,562,817 B1). Claims 8-10, 17, 19, and 21-23 are canceled, thus rendering rejection thereof moot. Applicants respectfully traverse the rejection applied to pending claims 1-4, 6-7, 11-12, 14-16, 18, and 20. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Applicants submit herewith a Terminal Disclaimer over U.S. Patent 6,562,817 in compliance with 37 C.F.R. § 1.321(c). Thus, the instant rejection is overcome.

***Duplicate Claims***

The Examiner asserts that claims 17 and 18 are substantial duplicates of claim 1. Claim 17 is canceled, thus rendering



rejection thereof moot. Applicants respectfully traverse the rejection applied to claim 18. Reconsideration of the claim and withdrawal of the instant rejection are respectfully requested.

Claim 18 is amended into a method claim dependent from claim 1. Claim 18 serves to further limit the subject matter of claim 1 by specifying that the disease is selected from the group consisting of ulcerative colitis, systemic lupus erythematoses, lupus nephritis, and rheumatoid arthritis.

Since claim 18 further limits the subject matter of claim 1, claim 18 is properly dependent upon claim 1. Withdrawal of the instant rejection is therefore respectfully requested.

### **Conclusion**

Applicants respectfully submit that the above remarks and/or claim amendments render the present application into condition for allowance. The Examiner is respectfully requested to issue a Notice of Allowance indicating that claims 1-4, 6-7, 11-12, 14-16, 18, 20, and 24 are allowed.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at the telephone number of the undersigned below, to conduct an

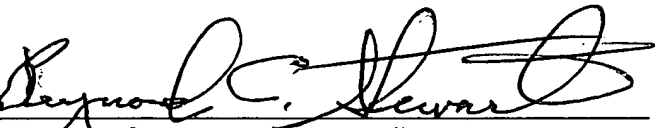


interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachments: Form PTO-1449  
Verified translation of JP 11-209298  
Exhibit 1 (Funauhi et al., Scand. J. Rheumatol., 1998;27(3):219-224);  
Exhibit 2 (Ehrenfeld et al., Lupus. 2001;10(9):622-627);  
Exhibit 3 (Boirivant et al., The Journal of Experimental Medicine, Volume 188, Number 10, November 16, 1998, 1929-1939)